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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,588	05/04/2001	Shigeaki Kato	046124-5006-01-US	1925

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EXAMINER

MURPHY, JOSEPH F

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/848,588

Applicant(s)

KATO ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7,8 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,14,15 and 17 is/are rejected.
- 7) ☒ Claim(s) 8 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Formal Matters***

Claims 7-8 and 14-17 are pending and under consideration.

### ***Response to Arguments***

The rejection of claims 8 and 16 under 35 USC § 112 second paragraph has been withdrawn.

The rejection of claims 7-8, 15-16 under 35 U.S.C. 102(a) as being anticipated by Pouponnot et al. (1998) has been withdrawn based on the English translation of the priority document.

The rejection of claims 7-8, 14-17 under 35 U.S.C. 102(a) as being anticipated by Janknecht et al. (1998) has been withdrawn based on the English translation of the priority document.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 7, 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu et al. (1997).

Liu et al. teaches that upon ligand binding, the receptors of the TGFbeta family phosphorylate Smad proteins, which then move into the nucleus where they activate transcription. To carry out this function, the receptor-activated Smads 1 and 2 require association

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with Smad4. Liu et al. investigated the step at which Smad4 is required for transcriptional activation. Receptor-activated Smad2 takes Smad4 into the nucleus where they form a complex with FAST-1 that requires these three components to activate transcription (page 3158, column 2, second paragraph). In the specification (see page 6, line 1) it is disclosed that a Smad molecule may serve as a transcription coupling factor. Liu et al. teach a method whereby a cell is cotransfected with expression vectors that code for Smad2 (a Smad molecule) as well as Smad 4 (which is functioning as a transcription coupling factor) (see page 3161, Figure 4D). In this method the expression vector coding for FAST-1 is also cotransfected (thereby added to the culture system), and the effects of the coexpression of FAST-1 on the binding of Smad2 to Smad4 are measured, thus the claims are anticipated.

Claims 7, 14-15, 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Nakao et al. (1997).

Nakao et al. teaches that Smad family members are newly identified essential intracellular signalling components of the transforming growth factor-beta (TGF-beta) superfamily. Smad2 and Smad3 are structurally highly similar and mediate TGF-beta signals. Smad4 is distantly related to Smads 2 and 3, and forms a heteromeric complex with Smad2 after TGF-beta or activin stimulation (page 5354, column 1).

In the specification (see page 6, line 1) it is disclosed that a Smad molecule may serve as a transcription coupling factor. Nakao et al. Teaches a method whereby a cell is cotransfected with combinations of Smad molecules, and the binding is measured by co-immunoprecipitation (see page 5357, Figure 5C). In this method, the cells are cotransfected with expression vectors

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coding for Smad 3 and Smad4. Here, Smad4 is serving as the transcription coupling factor. The substance added to the culture medium is TGF-b, and the effect on binding is measured, thus claims 7, 14 are anticipated.

Nakao et al. also teach a method whereby a cell is cotransfected with expression vectors coding for Smad2, Smad 3 and Smad4 (see page 5359, Figure 8). Dominant-negative Smad3 inhibited the transcriptional synergistic response by Smad2 and Smad4. In this method Smad4 is serving as the transcription coupling factor, while the effect of the substance added to the culture medium, i.e. TGF-b, is measured by the luciferase activity, thus claims 15 and 17 are anticipated.

### ***Conclusion***

Claims 7, 14-15, 17 are rejected.

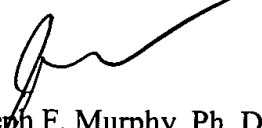
Claims 8, 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

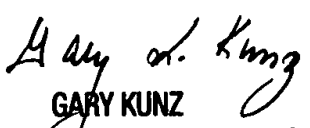
### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
May 28, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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